SHARED DECISION MAKING FOR PROSTATE CANCER SCREENING

15TH ANNUAL MASSACHUSETTS PROSTATE CANCER SYMPOSIUM

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• The Foundation has a licensing agreement with Health Dialog
  • Provides royalties and contract funding to develop and maintain decision support materials
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  • Staff and Medical Editors are prohibited from financial support from the drug and device industries
CLINICAL CASE

• A 50 year old man presents for a primary care visit soon after his birthday
• No other risk factors for prostate cancer
• Maybe he asks about prostate cancer screening...
• And maybe he doesn’t!

CLINICAL CASE

• How should the visit unfold? Should the option of screening be raised by the clinician if the patient doesn’t?
• Is PSA screening a choice? Is a DRE a choice?

WHAT'S THE LATEST EVIDENCE?

- US PLCO Trial (Update 13 yr)
  - For men 55-74 (N=76,685, annual PSA/DRE)
  - No difference in overall mortality
  - Diagnosis of PCa increased from 9.9% to 11.1% with screening
  - Risk of getting PCa increased 12% (95% CI 7%, 17%)
  - Risk of PCa death similar at 0.4% in both groups
  - RR PCa death 9% higher with screening (95% CI, 13%, +36%)
  - Problem with the PLCO trial
    - “Contamination” of the control group with “usual care” PSA tests may have obscured a small benefit

Andriole, et al. JNCI 2012;104:125
WHAT'S THE LATEST EVIDENCE?

- ERSPC Trial (Update 11 yr F/U NEJM 2012;366:981)
  - For men 55-69 (N=162,388, PSA-q 4 yrs, no DRE)
    - Diagnosis of PCa increased from 6.0% to 9.6% with screening
    - Risk of getting PSA increased 63% (95% CI 57%, 67%)
    - Risk of prostate cancer death decreased from 0.5% to 0.4%
    - Risk of PCa death decreased 21% (95% CI 32%, 9%)
  - Problem with the ERSPC trial
    - Men in the screening group were treated in different places than men in the control group when they were diagnosed with prostate cancer

EFFECTIVENESS OF THERAPY

- Scandinavian RCT of RP vs. watchful waiting, localized cancer
- <10% of PCa detected through screening
- Reduced PCa specific mortality from 21% in the WW group to 15% in RP group compared to WW at 15 years (P=0.01, NNT=15)
- Overall mortality reduced 53% to 46% at 15 years (P=.007, NNT=15)
- Benefit confined to men under 65 (NNT=7)
BREAST VS. PROSTATE CANCER SCREENING

• Per 10,000 screened for 10 years:

<table>
<thead>
<tr>
<th></th>
<th>Breast Cancer (age 40-69)</th>
<th>Prostate Cancer (age 55-69)</th>
</tr>
</thead>
<tbody>
<tr>
<td># biopsies</td>
<td>800</td>
<td>2,400</td>
</tr>
<tr>
<td># extra CA diagnosed</td>
<td>50</td>
<td>350</td>
</tr>
<tr>
<td># lives saved</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td># screened/life saved</td>
<td>2,000</td>
<td>1,400</td>
</tr>
<tr>
<td># treated/life saved</td>
<td>10</td>
<td>50</td>
</tr>
</tbody>
</table>

Gotzsche et al. Cochrane Database. 2006.
Elmore et al. NEJM. 1998;338:1089.
Schroder et al. NEJM. 2009;360:1320.

MORBIDITY OF XRT OR RP AT 5 YEARS

<table>
<thead>
<tr>
<th>Complication</th>
<th>XRT</th>
<th>RP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incontinence (requiring pads)</td>
<td>4%</td>
<td>29%</td>
</tr>
<tr>
<td>Erections insufficient for intercourse</td>
<td>64%</td>
<td>79%</td>
</tr>
<tr>
<td>Bothered by bowels</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Additional treatment (w/in 2-4 years)</td>
<td>24%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Potosky et al. JNCI. 2000;92:1582.
2008 MEDICARE RP OUTCOMES STUDY

800 RP pts from Medicare
3 found ineligible

685 / 797 surveys returned (86%)

38 not sure/no answer
220 surgery was not lap, assumed open
427 confirmed surgery was lap

406 confirmed robot assisted
9 not robot assist
12 not sure about robot assist

SIDE EFFECTS BOTHER BY SURGICAL TYPE

- Continence, moderate or big problem:
  - 27% open group vs. 34% robotic group (P=0.087)
- Sexual function, moderate or big problem:
  - 89% open group vs. 88% robotic group (P=0.57)

Barry et al. JCO. 2012;364:1708.
NEW DATA ON EFFECTIVENESS OF THERAPY

- U.S. PIVOT RCT of RP vs. observation, localized cancer (N=731)
- Most PCa detected through screening
- Reduced overall mortality by 3 fewer per 100 men treated in RP group compared to OBS at 12 years (P=NS, NNT=33)
- Significant interaction for baseline PSA <10 ng/mL vs. >10 ng/mL


WHAT WE (PROBABLY) KNOW FOR SURE:

- Prostate cancer screening doesn’t “save lives” in terms of reducing overall mortality…but it may reduce the risk of dying of prostate cancer
- Most of the prostate cancer deaths in the trial populations have yet to be counted (70% deaths >age 75)
- Unlikely screening would decrease lifetime risk by more than 3% to 2% (not a 1% shot at immortality…)

WHAT WE (PROBABLY) KNOW FOR SURE:

• Overdiagnosis and overtreatment are major problems at the population level
• But it’s very hard to tell who has been overdiagnosed or overtreated at the individual level
• Need strategies to reduce overdiagnosis and/or uncouple overdiagnosis from overtreatment
  • Higher biopsy threshold?
  • Active surveillance/watchful waiting?

PCA SCREENING GUIDELINES (2012)

• ACS: Offer prostate cancer screening at 50, at 45 with risk factors (40 for very high risk) if >10 yr LE
• USPSTF: New recommendation against routine PSA screening men of for all ages
• ACP: Guidance statement pending after PLCO/ERSPC
• AUA: Start screening at 40! (of 23,587 PCa deaths among white men, 265 before age 55)
BACK TO THE CASE!
OPTIONS:

• Clinician could just check the PSA box on the lab slip, no discussion
• Don’t ask, don’t tell...
• If asked, discourage testing based on USPSTF draft “D” recommendation
• “Come back when you’re 55!”
• Shared decision making: “Have you heard about the PSA test for prostate cancer screening?”

A NEJM PERSPECTIVE PIECE

The NEW ENGLAND JOURNAL of MEDICINE

• Perspective: One Man at a Time – Resolving the PSA Controversy
  Mary F. McNaughton-Collins, MD, MPH
  Michael J. Barry, MD
THE 6 STEPS OF SHARED DECISION MAKING

• Invite patient to participate
• Present options
• Provide information on benefits and harms
• Assist patient in evaluating options based on their goals and concerns
• Facilitate deliberation and decision making
• Assist with implementation

WHAT FACTS SHOULD BE COVERED IN AN SDM DISCUSSION ABOUT PSA?

• According to ACS guideline:
  • PCa is an important health problem (3% lifetime risk, 5% for men with risk factors)
  • Screening with PSA+DRE can detect PCa at earlier stage
  • Screening may be associated with lower risk of dying of prostate cancer (evidence is conflicting)
  • Unclear which men detected by screening will benefit
  • Treatment can lead to urinary, bowel, sexual and other health problems
  • False positives and negatives possible

Wolf et al. CA Cancer J Clin. 2010;60:70.
WHAT FACTS SHOULD BE COVERED IN AN SDM DISCUSSION ABOUT PSA?

• Contd. from ACS guidelines:
  • Abnormal screening results require biopsies which can lead to complications and may miss significant cancer
  • Not all men with PCa detected by screening need treatment, but do need close monitoring
• I’d add:
  • Men who choose regular PSA testing will substantially increase their risk of eventually getting prostate cancer, probably from around 8 in 100 without screening to 16 in 100 with screening

Wolf et al. CA Cancer J Clin. 2010;60:70.

WHAT VALUES SHOULD BE COVERED IN AN SDM DISCUSSION ABOUT PSA?

• What matters to you?
  • Doing everything possible to avoid dying of prostate cancer, even if we’re not sure PSA can do that?
  • Only doing things of proven benefit?
  • Avoiding a prostate biopsy?
  • Keeping your sexual and urinary function?
• Are you ready to decide?
• How about: “What would you do if you were me, doc?”
CAN DECISION AIDS HELP?

• In 86+ trials in 6 countries of 34 different decisions, decision aid use has led to:
  • Greater knowledge
  • More accurate risk perceptions
  • Lower decision conflict
  • Greater participation in decision-making
  • Fewer people remaining undecided
  • 15% fewer men choosing PSA tests


OHRI DECISION AID INVENTORY

• Ottawa Health Research Institute Inventory of patient decision aids:
  • Access information for over 500 decision aids
  • Includes IPDAS ratings

http://decisionaid.ohri.ca/index.html
WHAT ABOUT MALPRACTICE RISK?

- Percentage of mock jurors who felt the standard of care had been met when a PSA test was not done and the patient later presents with metastatic prostate cancer:
  - 17% when there is no note in the chart
  - 72% when a note in the chart reads, "Risks and benefits of PSA test discussed, patient declines."
  - 94% when a note in the chart reads, "Patient viewed PSA decision aid, questions answered, declines test."


TEACHING POINTS

- PSA screening is a "preference-sensitive" decision...reasonable, informed men can make different choices
- Six steps of shared decision making
- Decision aids can help make SDM practical
- Watch for the PIVOT trial results!
THANK YOU!

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